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MAY 18 2009

Section E – Special 510(k) – Summary
(*Additional Information Requested* - Section E – page 1 of 3)

In Accordance with 21 CFR Section 807.92 Power Medical Interventions, Inc., is submitting the following 510(k) Summary:

1) Submitter Information:

Power Medical Interventions, Inc.
2021 Cabot Blvd.
Langhorne, PA 19047
Ph: 267-775-8151
Fax: 267-775-8123

Applicant: Barbara J. Whitman

Date of Notification: April 24, 2009

2) Name of Device:

Trade Name:	Intelligent Power Unit (iDrive) with Intelligent Console (iConsole), Intelligent Delivery Systems (iStraight, iCurve, iFlex), and Intelligent Surgical Instruments (i45, i60, i60XXL, i45R, i60R, i45V, iNOLC 45, iNOLC60)
Common Name:	Surgical Staplers with Implantable Staples
Classification Name:	Staple, Implantable, GDW

3) Predicate Device:

iDriveS, iDriveC, iDriveF, Power Medical Interventions, Inc., Langhorne, PA. REF iDriveS, iDriveC, iDriveF (K073001).

iDrive with Vascular Indications, Power Medical Interventions, Inc., Langhorne, PA. REF iDriveS, iDriveC, iDriveF (K073148).

Intelligent Articulating Endoscopic Linear Cutters with Reloads, Power Medical Interventions, Inc., Langhorne, PA. REF i45, i45S, i60, i60S (K071708).

4) Device Description:

The iDrive with iConsole is used in conjunction with the Intelligent Delivery Systems and Intelligent Surgical Instruments in order to resect tissue, transect tissue and create anastomoses between structures. The iDrive was previously cleared to market via K073001 and was subsequently cleared to market with additional vascular indications via K073148. The iDrive is a handpiece with integrated controls that operate the attached Intelligent Delivery Systems and Intelligent Surgical Instruments.

5) Device Modification

The iDrive with iConsole, when used in conjunction with the Intelligent Delivery Systems and Intelligent Surgical Instruments, functions identically to the predicate devices iDriveS, iDriveC, iDriveF (K073001), iDrive with Vascular indications (K073148), and Intelligent Articulating Endoscopic Linear Cutters with Reloads (K071708). The iDrive was modified so that the Intelligent Surgical Instruments and the Intelligent Surgical Instruments are detachable from the handpiece.

6) Indications For Use

The iDrive Intelligent Power Unit with iConsole, when used with:

a) compatible Intelligent Surgical Instrument Linear Staplers , have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal, and thoracic surgical procedures for resection, transection, creation of anastomoses, and for open occlusion of the heart's left atrial appendage.

b) compatible Intelligent Delivery Systems (iStraight, iFlex, iCurve) and Right Angle or Power Linear Cutter Digital Loading Units®, has applications in gastrointestinal, gynecological, general abdominal, and thoracic surgical procedures for resection, transection, and creation of anastomoses.

c) compatible Intelligent Delivery Systems and Circular Stapler Digital Loading Units®, has applications for use throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

d) compatible Vascular Intelligent Surgical Instruments or Intelligent Delivery Systems with Vascular Digital Loading Units®, has applications for general and endoscopic surgery including multiple open and minimally invasive general, gynecological, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures for

resection, transection, and/or creation of anastomoses. They can be used with staple line buttressing material such as bovine pericardium.

7) Comparison to Predicate Devices

The iDrive with iConsole is used in conjunction with the Intelligent Delivery Systems and Intelligent Surgical Instruments and functions identically to the predicate devices. The electronics, power configuration, and internal gearing & transmission are common to both predicate and subject devices. Both the predicate and subject devices are powered mechanically by rotational energy. In both the predicate and the subject device, a clamp shaft drives a clamp screw, which causes the anvil to close and compress tissue. The same is true for firing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Power Medical Interventions, Inc.
% Ms. Barbara J. Whitman
Director, Regulatory Affairs
2021 Cabot Boulevard West
Langhorne, Pennsylvania 19047

Re: K091215
Trade/Device Name: iDrive Intelligent Power Unit with iConsole
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: April 24, 2009
Received: April 27, 2009

Dear Ms. Whitman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D - *Indications for Use*

(*Additional Information Requested* - Sectio D - page 1 of 4)

510(k) Number (if known): K091215

Device Name: iDrive Intelligent Power Unit with iConsole

Indications For Use

The iDrive Intelligent Power Unit with iConsole, when used with compatible Intelligent Surgical Instrument Linear Staplers , have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal, and thoracic surgical procedures for resection, transection, creation of anastomoses, and for open occlusion of the heart's left atrial appendage.

Prescription Use ____x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091215

Section D - *Indications for Use*

(*Additional Information Requested* -Section D - page 2 of 4)

510(k) Number (if known): K091215

Device Name: iDrive Intelligent Power Unit with iConsole

Indications For Use

The iDrive Intelligent Power Unit with iConsole, when used with compatible Intelligent Delivery Systems (iStraight, iFlex, iCurve) and Right Angle or Power Linear Cutter Digital Loading Units®, has applications in gastrointestinal, gynecological, general abdominal, and thoracic surgical procedures for resection, transection, and creation of anastomoses.

Prescription Use ____x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091215

Section D - *Indications for Use*

(*Additional Information Requested* -Section D – page 3 of 4)

510(k) Number (if known): K091215

Device Name: iDrive Intelligent Power Unit with iConsole

Indications For Use

The iDrive Intelligent Power Unit with iConsole, when used with compatible Intelligent Delivery Systems and Circular Stapler Digital Loading Units®, has applications for use throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

Prescription Use ____x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091215

Section D - *Indications for Use*

(*Additional Information Requested* -Section D – page 4 of 4)

510(k) Number (if known): K091215

Device Name: iDrive Intelligent Power Unit with iConsole

Indications For Use

The iDrive Intelligent Power Unit with iConsole, when used with compatible Vascular Intelligent Surgical Instruments or Intelligent Delivery Systems with Vascular Digital Loading Units®, has applications for general and endoscopic surgery including multiple open and minimally invasive general, gynecological, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures for resection, transection, and/or creation of anastomoses. They can be used with staple line buttressing material such as bovine pericardium.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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